

REMARKS

Claims 78, 80-83, 90-91 have been cancelled and new claims 92-103 have been added. In addition, claim 63 has been amended to clarify the step of inhibiting recited in base claim 62, and claim 64 have been amended to correct the dependency upon claim 63. Finally, new claims 92-103 have been added. New claims 92-103 ultimately depend from claim 62, and parallel those claims depending from claim 18 in Group I. Accordingly, no new matter has been added by way of these amendments.

Response to restriction requirement under 37 C.F.R. §§ 1.142 & 1.143

In the above-captioned patent application, the Examiner has issued a restriction requirement, restricting the invention to one of the following four groups:

- I. Claim 18-32 drawn to a method of enhancing cognitive function in warm-blooded vertebrae,
- II. Claims 62-64, drawn to a method of treating cognitive disorders in warm-blooded vertebrae,
- III. Claims 78, 80, 81, 82, 83, 90-91 drawn to the method of using in the manufacturing of a medicament of a medicament an inhibitor of the peptidase activity ingredient in a cognition enhancing composition in mixture with a pharmaceutically acceptable carrier.
- IV. Claim 78-83, 90-91 drawn to the use, in the manufacture of a medicament of an inhibitor of the peptidase activity of N-acetylated- α -linked-acidic dipeptidase as the active ingredient.

The Examiner contends that each of the inventions defined by Groups I-IV are independent and distinct from each other. The Examiner further contends that inventions I, II, and III are directed to related methods of inhibiting peptidase activity. Further, the Examiner contends that invention IV encompasses “use claims” that may be construed to be either product or process claims and that invention III encompasses these said “use claims.” For the purpose of restriction, the Examiner indicates that the claims of invention III are being interpreted as product claims for Group IV and that Group IV and Group III are related as product and process of use. Finally, the Examiner has indicated that the product claims

and the process claims, though currently restricted in the Office Action, may be rejoined upon allowance of the product claims pursuant to MPEP § 821.04.

Applicant respectfully traverses the restriction requirement restricting the claims divided into Groups I and II. Applicant points out that the inventions in Group I and Group II delineated by the Examiner relate, in fact, to a single invention and are not independent and distinct as the Examiner suggests. Applicant believes that this relationship is clear when it is considered that each of the claim Groups I and II shares a substantial technical feature in common. Namely, the inventions of Groups I and II are drawn to improving cognition in warm-blooded vertebrates, and differ only in the point of reference from which that improvement in cognitive function may be evaluated. In particular, the invention of Group I is directed to increasing cognitive function in any patient to an elevated level, including those patients that may be perceived as having “normal” level of cognitive performance prior to treatment. The invention of Group II is directed to increasing cognitive function in a warm-blooded vertebrate that is suffering from or in need of relief from a disease state that adversely affects cognitive performance. Therefore, each of the inventions is directed toward a treatment that may result in an improvement in the cognitive abilities of the treated patient. Thus, Applicant believes that the claims of Groups I and II should be examined together as a single group. Accordingly Applicant considers that the inventions segregated by the Examiner into Groups I and II are not independent and distinct, as defined by 35 U.S.C. § 121 and 37 C.F.R. § 1.141, and therefore should not be restricted. Reconsideration of the instant restriction requirement leading to its withdrawal is respectfully requested.

However, should the Examiner nevertheless maintain the restriction requirement, Applicant elects herein the invention of Group II. Further, Applicant respectfully requests that new claims 92-107, depending from claim 62, the base claim in Group II, be joined with the invention of Group II for examination.

Election of species under 37 C.F.R. § 1.146

The Examiner has also required an election of species for each of Groups I-IV. The Examiner has indicated that Applicant is required to elect (i) one compound capable of inhibiting the peptidase activity of one or more neurogenic peptidases in the brain, (ii) one

disease state, (iii) one species of warm-blooded vertebrate, and (iv) one pharmaceutical formulation. Applicant also traverses the election of species required by the Examiner.

Regarding the elected Group II, Applicant respectfully points out to the Examiner that β -lactam compounds, β -lactam antibiotics, and β -lactamase inhibitors are well known to a person of ordinary skill in the art, and many of these compounds share a common structural feature, namely a β -lactam heterocyclic ring moiety. Therefore, it is Applicant's suggestion that at least insofar as β -lactam compounds, β -lactam antibiotics, and β -lactamase inhibitors are concerned, a search of these compound classes would not be burdensome on the Examiner. Accordingly, Applicant believes that an election of a single species of compound is not required here, and that the examination of the elected Group II may take place without such an election. Accordingly, Applicant respectfully requests that the election of species for the single compound be reconsidered and withdrawn. If however an election of a specific β -lactam is nevertheless required in Group II, Applicant elects herein the compound moxalactam as the species.

The Examiner has also required Applicant to elect one species of warm-blooded vertebrate. The Examiner suggests that because warm-blooded vertebrates have "different genetic characteristics," an election requirement is proper here. Applicant respectfully points out that even between two human patients that are not identical twins, there are different genetic characteristics. Therefore, such a basis for requiring an election of species is improper. Instead, Applicant believes that the more important observation is that warm-blooded vertebrates, as distinguished from insects for example, share many physiological and biochemical features in common. It is those similarities that allow for the examination of warm-blooded vertebrates as a group rather than necessitating an election of species to a single warm-blooded vertebrate. Accordingly, Applicant respectfully requests that the election of species for the warm-blooded vertebrate be reconsidered and withdrawn. If however an election of a specific warm-blooded vertebrate is yet required in Group II, Applicant elects herein human as the species.

The Examiner has also required Applicant to elect one species of disorders. Applicant elects herein Alzheimer's disease as the species.

The Examiner has also required Applicant to elect one species of pharmaceutical formulations. More specifically, the Examiner has required Applicant to elect one exact pharmaceutical formulation for examination purposes wherein each active

ingredient(s), pharmaceutical carrier(s), and the amounts of each ingredient(s), as well as the corresponding effective dosage of the pharmaceutical formulation, is specifically defined. Although the Examiner has indicated that an election is required here, based on the Examiner's reference to each of Groups I-IV in the Office Action, Applicant does not believe an election is appropriate here for Group II. Instead, Applicant suggests that the Examiner intended this election to only apply to the invention of Group II or that of Group IV. Each of Groups III and IV contemplate a pharmaceutical composition, which is more consistent with such a burdensome election of species requirement. In contrast, Group II recites a method, and that method is not dependent upon any particular route of administration nor on any particular formulation. The claim contemplates all routes of administration and formulations. Applicant respectfully suggests that the effective examination of the claims of Group II is not burdened by absence of such a specific selection of a formulation. Even should the Examiner rejoin Group I with elected Group II, Applicant does not believe an election of a formulation of the inhibitor would facilitate examination of the pending claims because Group I, like Group II, recites a method that is not dependent upon any particular route of administration nor formulation. Therefore, because Group II is elected herein, and moreover because the claims of Groups III and IV have been canceled, Applicant does not believe an election is necessary. Accordingly, Applicant respectfully requests that the election of species of a single formulation be reconsidered and withdrawn. If however an election is yet required in Group II, Applicant elects moxalactam at a dosage of 50 $\mu\text{g/kg}$ of patient body weight in a 0.9% NaCl aqueous carrier.

Pursuant to 37 C.F.R. § 809.02(a), Applicant indicates that claims 62-64, 95-99, 101-103 are readable on the elected species. Applicants believe that the claims are in condition for allowance, and respectfully request that the application be passed to issue.

Respectfully submitted,
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